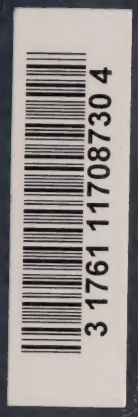
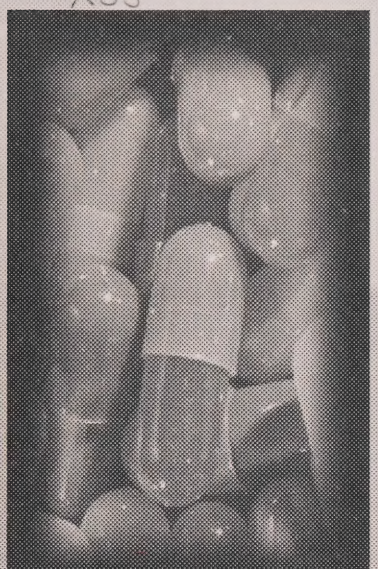


Road Map for the Next Decade: Report on the PMPRB's Public Consultation



Patented Medicine
Prices Review Board

CANADA

Conseil d'examen du prix
des médicaments brevetés

Road Map for the Next Decade

Report on the PMPRB's Public Consultations

The PMPRB contributes to Canadian health care by ensuring that prices of patented medicines are not excessive.

1998

The Patented Medicine Prices Review Board
Standard Life Centre
Box L40
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Telephone: (613) 952-7360
Facsimile: (613) 952-7626
TTY: (613) 957-4373

Toll-free number: 1-877-861-2350

Visit us at our Web site: http://www.pmprb-cepmb.gc.ca

All PMPRB publications are available in both official languages.
Please contact us to obtain our publications.

Table of Contents

1. MESSAGE FROM THE BOARD

The Patented Medicine Prices Review Board (PMPRB) is pleased to report on the results of its consultations regarding the examination of the role, function and methods of the PMPRB. It was a pleasure to have the opportunity to meet with many of the Board's stakeholders as we travelled across the country for our information meetings, and then, again, in Ottawa during our public policy hearing. These stakeholders include Canadians from all walks of life be they individual consumers, health care professionals, seniors groups, consumer groups, patient advocacy groups, private insurers, trade associations, provincial governments or pharmaceutical companies and their consultants.

The PMPRB is committed to continuing to play a positive and effective role in serving the interests of Canadians.

Dr. Robert G. Elgie, Chairperson, PMPRB

A key factor contributing to the success of the consultation process was the participation of the range of stakeholders and their suggestions and comments. We were impressed by the number of written submissions and oral presentations. Included as appendices to this report are lists of the public information meetings held by the Board, the submissions received, and the appearances at the Board's policy hearing. All submissions and the proceedings of the policy hearing are on the public record.

The Board would like to thank all stakeholders for their participation and suggestions. Our review and renewal process has been enriched by the ideas that stakeholders have put forward. We can only hope that the expression of interest which was so evident during our consultations continues, as we consider proposals to adjust the Board's policies and procedures. Change is desirable and necessary to make the Board responsive to the needs of Canadians and to foster confidence in the system. The process of change may not always be easy and may take time to implement properly. We ask stakeholders to bear with us as we proceed forward. It is in anticipation of continued stakeholder participation that we will chart the way ahead for the PMPRB to ensure it continues to play a useful role in the Canadian health system.

2. CONTEXT

a) The Consultation Process

The report of the Standing Committee on Industry, released in April 1997 following its review of Bill C-91, underscored the concerns of Canadians about the cost of drugs and its impact on the health care system. The report also touched on a number of key areas directly affecting the role and mandate of the PMPRB. One of the recommendations made by the Standing Committee was that the PMPRB should consult with stakeholders to assess its current statistical reporting, and to determine what other information might be gathered and shared with the public:

> To facilitate the public debate on the pricing, usage and costs of drugs, as well as on pharmacare, the Committee recommends that the PMPRB consult with consumers, health care professionals, experts and the provinces to assess its current statistical reporting, and find out what other information it could provide to the public.
>
> *Fifth Report of the Standing Committee on Industry, April 1997*

The PMPRB commenced an internal review of its activities in May 1997, immediately after the release of the Committee's report. The purpose was to examine existing functions and identify the best means of addressing the Standing Committee's recommendations.

The Board concluded that there was a need to go out to its stakeholders to get their input on how the Board should address the manner in which it fulfills its mandate within the context of the Canadian health care system. The approach adopted by the Board differed from previous consultation exercises. In order to obtain a broader representation of perspectives and ideas into the policy development process, the Board reached out, in particular, to those stakeholders who had not traditionally participated actively in previous consultations, including consumers, seniors and patient advocacy groups.

The first step in this comprehensive consultation process involved the release in November 1997 of a discussion paper entitled *"Examining the Role, Functions and Methods of the PMPRB"*. More than 2,000 copies of this discussion paper were distributed. The paper looked at the PMPRB and discussed a number of central themes, such as drug prices and cost issues, strengthening public accountability, pricing methods and guidelines.

In February and early March 1998, public information sessions were held in all provinces and territories. Close to three hundred people, many of whom represented larger organizations, attended the sessions which were held in thirteen cities. These sessions provided the Board with the opportunity to present an overview of its current role and responsibilities, to hear what stakeholders had to say about its role, function and methods, and to answer questions. The goal was to provide background information in order to facilitate discussion on the Board's future directions.

To further support the consultation process, the PMPRB invited written submissions to be filed by the end of March 1998. Sixty-one substantive submissions were received from interested individuals and organizations. On April 30 and May 1, 1998, a public policy hearing was held in Ottawa. During the hearing, 24 organizations or individuals appeared before the Board and made representations in support of their written submissions.

This report is the second step in the consultative process. It provides a summary of the concerns of stakeholders, and the actions that have been taken to date. It also provides an outline of the measures that we will be taking in order to act on the issues raised by stakeholders. There is a plan of action with clearly established time frames for each task.

The next stage of the process will be further consultations on specific issues as well as the research agenda. Stakeholders will be consulted on proposed changes to the Guidelines or policies before the Board adopts any changes to them.

b) Stakeholders' Concerns: Overview

[The misconception] that the PMPRB should control the total cost of medicines... is a result of confusing the price of drugs and the cost of drugs, as if they were the same thing. They are not. ...The total cost of medicines reflects a multiplicity of factors, such as: the number of beneficiaries; the population health status (associated with poverty); the life expectancy; the new diseases to be treated (AIDS); the old diseases to be treated (Alzheimer's); the old diseases to be treated better (mental disorders); the prescribing profile (prescribing a Mercedes when only a bus ticket is needed); the overuse of medications; the prices of medicines and their evolution. These factors explain why the total costs of drugs could increase dramatically, while the prices of drugs could be contained.

Dr. Robert Goyer, Dean, Faculty of Pharmacy, University of Montréal

It was apparent from the consultation process that there is much interest in the role of the PMPRB, as evidenced by the stakeholder participation. Throughout the process, stakeholders have indicated that they want to be involved in the way the PMPRB carries out its mandate.

The familiarity of stakeholders with the Board's mandate and policies varies considerably. Some stakeholders are very knowledgeable, while others have varying degrees of understanding. Likewise, some understand the "drug price versus cost" issue, while others feel that a clarification of terminology would be useful.

Some stakeholders believe that the Guidelines are more than adequate to carry out the Board's mandate and may even be too restrictive; others are concerned that they may allow introductory prices that are too high.

Since the beginning of the consultation process, the Board's focus has been on those issues related to how the PMPRB fulfills its mandate. The Board also heard many submissions from stakeholders about matters they wished changed which are matters of government policy. Although many of these issues are not within the Board's jurisdiction, they have been included in this report in order to make the Ministers of Health and Industry aware of what people throughout the country have said regarding government policy on pharmaceuticals. The program administered by the PMPRB is simply one element of overall government policy with respect to pharmaceuticals.

3. WHAT STAKEHOLDERS ARE SAYING ABOUT CANADA'S PHARMACEUTICAL POLICY AND THE PMPRB'S MANDATE

This section reports on those matters raised by stakeholders to be brought to the attention of the government and the public at large. The Board is committed to doing further work on these matters if the government requests and supports such activity by the Board.

a) Scope of the PMPRB's Mandate

> ... our commitment has been that those issues related to mandate ... and any of the feedback that we get ... is definitely going back to the Minister in our report, which goes not only to the Minister but to everybody else who has been involved in this process.
>
> *Dr. Judith Glennie, Board Member, PMPRB, Public Policy Hearing*

The Board heard from many Canadians that they want to see the Board have a larger role, not only to control the prices charged by manufacturers of patented drugs, but to have a larger influence on total drug expenditures in Canada.

Many think that there should be regulation of the manufacturers' prices of all drugs, including non-patented single source drugs and generic drugs.

> [While we] understand that the issue of including non-patented medicines within the jurisdiction of the PMPRB is not one the Board can determine unilaterally, it is important that this issue be carried forward into the PMPRB's discussions with the federal, provincial and territorial committees and federal legislators. As an increasing number of generic drugs are included on provincial and private formularies, they must also come under scrutiny to ensure they meet standards similar to those required of brand name manufacturers. CAS recommends that generic drugs be subject to the jurisdiction and policies of the Patented Medicine Prices Review Board.
>
> *Mr. Rodney Kort, Canadian AIDS Society, Public Policy Hearing*

> A publicly accountable and transparent price regulator should have a mandate covering all pharmaceutical products.
>
> *Ms. Kathleen Connors, Canadian Health Coalition, Public Policy Hearing; Newfoundland and Labrador Health Care Association, Council of Senior Citizens' Organizations of British Columbia, written submissions*

> ... broaden the PMPRB's role to include regulation of non-patented medicines.
>
> *Canadian Healthcare Association, written submission*

> ... the PMPRB should also set and monitor prices for generic drugs.
>
> *Canadian Association of Retired Persons, written submission*

> We feel that the Board can play a useful role in providing public scrutiny of the prices of non-patented brand name drugs and non-patented generic drugs.
>
> *Mr. Vernon Chiles, Green Shield, Public Policy Hearing*

> We believe it would be in the best interest of our customers that the scope of the PMPRB's mandate be expanded to include jurisdiction over patent pending and non-patented drugs.
>
> *Alberta Blue Cross, written submission*

> It would be imperative to reduce the silo effect which only allows PMPRB to purview the patented medicines; that restriction ought to be abandoned. We would therefore recommend that, as an initial step, PMPRB assess the impact of current drug price competition in the Canadian market, and if this competition does not impact upon generic prices significantly, that the mandate should then be expanded as previously recommended. When we say "all drugs", we would like you

to understand that we are not really including the non-prescription drugs; we are really looking at the prescription area.

Mr. Leroy Fevang, Canadian Pharmacists Association, Public Policy Hearing

... expand the scope of the Board's mandate to include price regulation of non-patented medicines.

Canadian Nurses' Association, written submission

The findings of the Federal/Provincial/Territorial Task Force on Pharmaceutical Prices suggest that prices of these non-patented single-source prescription medicines have risen faster than patented medicines. At the C-91 hearings my predecessor indicated a willingness to co-operate and to inter-delegate the required authority to allow the Board to take this on for Saskatchewan.

Hon. Clay Serby, Minister of Health, Saskatchewan, Public Policy Hearing

The costs and potential benefits of including single source non-patented drugs under the PMPRB framework should be explored.

B.C. Pharmacare, written submission

... would like to see the mandate of the Board expanded to include single source non-patented drug products.

NWT Health and Social Services, written submission

The pricing of non-patented medicines should also fall under the jurisdiction of PMPRB as this group of products represents a significant cost component to the Canadian public.

Nova Scotia Department of Health, written submission

The Board mandate needs to be broadened to include non-patented drugs. This needs to be done in conjunction with the provinces/territories.

Ontario Ministry of Health, written submission

On the other hand, a number of industry stakeholders were opposed to the expansion of the mandate of the PMPRB.

There is however, no evidence to suggest that the prices of non-patented medicines as a whole are excessive. [To include non-patented prescription medicines] would be an unwarranted burden for the sake of a few high profile cases that are only perceived to be excessively priced but for which the respective companies have not had the opportunity to provide any information.

Pharmaceutical Manufacturer's Association of Canada, written submission

CDMA opposes any suggestions for a broad-based expansion of PMPRB's mandate to include the review of non-patented, multi-source drugs.
Mr. Jim Keon, Canadian Drug Manufacturers' Association, Public Policy Hearing

... the mandate should not be expanded at this time.
Parke-Davis, written submission

b) Basket of Comparator Countries

Some stakeholders question the appropriateness of the current basket of comparator countries and encourage the government to broaden the number of countries used for comparison purposes.

We have concerns that the United States is one of the seven countries used to monitor the prices of the Category 2 drugs. We feel that there are more appropriate countries to be included, Australia for one; but to include the US, where there is no attempt to control prices, we feel distorts that calculation. All seven countries certainly have drug prices as high as we would encounter in any other industrial countries.
Ms. Jean Jones, Consumers Association of Canada, Public Policy Hearing

Some stakeholders made specific suggestions regarding the basket of comparator countries. A number of them believed that the current basket should be expanded from its current seven to include all OECD countries.

... make drug price comparisons against all 24 OECD countries, not just 2 or 3 of the top 7 as required in the current regulations.
Mr. John Solomon, M.P., Regina-Lumsden-Lake Centre, written submission

... the Board should look at the prices of comparable drug products in all 29 OECD countries and not just for the current group of seven.
Nova Scotia Government Employees Union, written submission

The introductory price of new drugs should reflect the OECD average, not the G-7 average.
Manitoba Society of Seniors, Council of Senior Citizens' Organizations of British Columbia, written submissions; Ms. Kathleen Connors, Canadian Health Coalition, Public Policy Hearing

Further suggestions regarding the composition of the basket included the selection of countries based on their similarity to Canada in the level of research and development.

> ... the Board expand its basket of countries for international price comparisons to include others bearing closer similarity to Canada's size and circumstance.
>
> *Canadian Nurses' Association, written submission*

> The level of R&D performed by the pharmaceutical companies in Canada should determine which basket should be used as an appropriate international comparator. Or if the current basket is maintained, an appropriate multiplier for introductory prices should be developed to reflect R&D levels.
>
> *B.C. Pharmacare, written submission*

> ... we should look again at what level of R&D it is realistic for Canada to achieve in the pharmaceutical area and that we should choose our comparator countries based on that.
>
> *Dr. Joel Lexchin, Public Policy Hearing*

It was also suggested that the basket of countries should be reviewed on a regular basis to ensure that it continues to meet the established objectives.

> The comparator countries should be reviewed and validated on a regular basis.
>
> *Mr. Bob Nakagawa, written submission*

> For international price comparisons, the basket of countries used in the comparison should be reviewed on an ongoing basis to ensure they comprise a representative group.
>
> *Nova Scotia Department of Health, written submission*

A smaller group of stakeholders, primarily the industry and its consultants, did not agree that the basket of countries should be expanded arguing that it would have little if any impact on prices, but would increase the burden on both the Board and the patentees.

Increasing the number of countries to include the 28 OECD countries would significantly increase the regulatory burden for patentees and Board staff but have little if any impact on prices. Therefore, Novartis strongly recommends the retention of the current seven comparator countries.

Novartis, written submission

c) General Pharmaceutical Policy Issues

Canadians are concerned with the increasing demand and usage of drugs. A number of stakeholders recognize that utilization is a key determinant in rising drug expenditures. They would like to see something done about this. Related to this is the issue of appropriate prescribing.

Concern was expressed over the coverage of drugs by existing drug plans. Many Canadians expressed an interest in developing a national pharmacare program or improving access for all Canadians to necessary drugs.

Certain patient advocacy groups were concerned with the impact on patients of arbitrary decisions by a manufacturer to discontinue a drug or delay bringing a new drug to market. They would like to see the government play a role in this area.

Several stakeholders voiced their dissatisfaction with the government's policy regarding pharmaceutical patent protection. They believe that this policy has led to higher prices. It was suggested that a rebalancing or a review of patent protection was necessary. On the other hand, a few stakeholders were of the view that the balance established by Parliament in 1987 and 1993 was in danger of being upset.

Some specific suggestions were made to facilitate more rapid approval by the Health Protection Branch, and, therefore, earlier marketing of generic drugs. Additionally, there were suggestions targeted to the provinces, such as improving provincial formulary approval systems for faster listing of generic drugs and repealing the "fifteen-year rule" in Quebec.

d) Pharmaceutical Research and Development

A further issue raised by stakeholders concerning the government's pharmaceutical policy and possible revisions to the PMPRB's mandate was the issue of research and development (R&D). As noted earlier, some argued that the selection of foreign countries used for price comparisons should be related to comparable levels of R&D spending in Canada and those countries.

Some industry stakeholders commented that the current R&D reporting is not comprehensive as it does not incorporate the R&D activities of patentees who have no product sales.

> The Board's reporting of Canadian R&D understates the true levels of R&D. This is because the expenditures of non-marketing patentees are excluded from the Board's figures, even though these are the very emerging companies that the government policies are trying to encourage and support.
>
> *Mr. Philippe Hébert, Merck Frosst, Public Policy Hearing*

Other stakeholders argued that a company's R&D performance should be taken into account in reviewing the prices of its products.

> The Board should strengthen the review process and parameters for price increases, including linking them to a company's R&D performance.
>
> *Nova Scotia Department of Health, written submission*

> Section 85 of the Patent Act should be amended to recognize the unique costs encountered by vaccine manufacturers in the research, development; and manufacture of vaccines.
>
> *Pasteur Mérieux Connaught Canada, written submission*

Representatives of the Canadian biotechnology sector argued that the current guidelines for breakthrough drugs, which limit the price in Canada to the median of foreign prices, are inappropriate for their industry.

> The current situation we are in in the industry is, though, that we are investing in Canada above average. ... My suggestion is that strong price rewards for Canadian companies should be used to reward them for investing in Canada.
>
> *Mr. D. Froom, Allelix Biopharmaceuticals, Public Policy Hearing*

It was acknowledged that while the pharmaceutical industry in Canada as a whole has met its target to spend 10% or more of its sales on research and development, there are many "free riders", individual manufacturers who spend much less.

Some stakeholders would like to see greater control over research spending by the pharmaceutical companies in Canada so that the value of such research could be assessed. Some would envisage a research fund managed by government, comprised of profits from the pharmaceutical industry.

e) Other Significant Comments

A few stakeholders believed that a more appropriate way to protect consumer interests, in terms of drug prices, would be to regulate the return on investment of each company or to regulate prices based on the costs of research and development and manufacturing.

> The United Kingdom has chosen not to focus on the price of drugs, but to limit the rate of return on investment and let the drug companies set prices within these limits. Such an approach could also be considered as protecting the consumers' interest and deserves to be debated when changes to the PMPRB's mandate is explored.
>
> *Dr. Joel Lexchin, written submission*

There were suggestions that the composition of the Board should be expanded to include consumers, nurses, hospital administrators and other health professionals.

A number of stakeholders referred to the audit of the PMPRB being carried out by the Auditor General of Canada. Some even suggested that it was not appropriate for the PMPRB to carry out its consultation process at the same time. The Board disagrees.

> ... government's activities can't come to a halt because an audit is being carried out in a specific portion of the government or an agency, and that's our view too. We have a job to do, and we will continue to do it. We don't look at the Auditor General's presence as a threat; we think it is an opportunity to see if he has some suggestions that might improve how we do business, but we don't intend to suddenly behave as if we were in trusteeship because of an ordinary, everyday activity of an audit being conducted, as they are conducted each year.
>
> *Dr. Robert G. Elgie, Chairperson, PMPRB, Public Policy Hearing*

f) Next Steps

The Board is honouring its commitment to stakeholders to pass on these concerns regarding pharmaceutical policy and its mandate to the Minister of Health and the Government of Canada by including them in this report. The Board remains prepared to study any of these questions if requested to do so by the government.

It should be noted that the Federal/Provincial/Territorial Task Force on Pharmaceutical Prices is conducting research and analysis on a number of issues, including price and expenditure trends of prescription drugs in various provincial drug plans. In addition, it is investigating the prices of single source drug products, both patented and non-patented. The PMPRB is providing expertise to, and conducting research for, the Task Force, including a study comparing the prices of top selling non-patented single source drug products in Canada and other countries.

The Task Force is expected to prepare a report to ministers of health later this year. In addition to reporting on its drug price research and analysis, the report is expected to address matters relating to the PMPRB that are the responsibility of the federal and provincial governments, such as the makeup of the basket of countries used to compare prices and the scope of the PMPRB's mandate.

4. WHAT STAKEHOLDERS ARE SAYING ABOUT HOW THE BOARD CARRIES OUT ITS MANDATE

Overwhelmingly, Canadians have been pushing the Board for greater transparency and greater accountability. This consultation process has already served to influence the way the PMPRB functions in terms of an increasing emphasis on availability, access and two-way communication.

> Proceedings of the PMPRB must be transparent and open to public scrutiny.
>
> *Canadian Association of Retired Persons, written submission*

The submissions of stakeholders concerning how the PMPRB carries out its mandate addressed issues related to transparency, accountability, and consultation as well as the price review process and methodologies.

a) Transparency and Accountability

Many stakeholders urged greater transparency in the way in which the Board carries out its mandate.

> We do see the consultation process as an effective model of increasing the transparency and identity of the PMPRB. I hope there is a further strengthening of public accountability as a consequence of the consultations. We feel that there is certainly room for more improvement in information and transparency and we feel that involvement of consumers in the process is a major way to effect improvement.
>
> *Ms. Jean Jones, Consumers Association of Canada, Public Policy Hearing*

> ... your Board operates under considerable secrecy, and drugs prices are still going up at an alarming rate.
>
> *Ms. Mary Eady, Congress of Union Retirees of Canada, Public Policy Hearing*

> The Board appears to carry an envelope of secrecy around itself and it would assist organizations such as ours to communicate openly with representatives once a year perhaps.
>
> *Canadian Society of Hospital Pharmacists, written submission*

> The question of having it done under full public scrutiny seems to me essential if we are really going to address the problems and know how together we can work on the solutions.
>
> *Ms. Mary Kehoe, Congress of Union Retirees of Canada, Public Policy Hearing*

> ... the core of the problem is that it is not publicly accountable and not visible enough and transparent in its work.
>
> *Mr. Michael McBane, Canadian Health Coalition, Public Policy Hearing*

> The apparent secrecy under which the scientific review process operates is a source of frustration.
>
> *Novartis, written submission*

b) Sharing Information and Collaborating with Stakeholders

Transparency was an issue both in terms of the availability of information and the processes, procedures and methodologies used by the PMPRB. A number of associations such as the Canadian Association of Retired Persons, the Canadian Diabetes Association and the Canadian Pharmacists Association proposed partnerships to assist in the dissemination of information.

The transparency of the price review process might be improved by publishing a semiannual report on the results of deliberations of the Board, i.e., hearings, voluntary compliance undertakings. These reports would help ensure that all stakeholders were aware of the activities of the Board. It would be helpful to have a clear explanation of how the categories of drugs are determined (particularly category 2).

Ontario Ministry of Health, written submission

The Board should provide further information to patentees about its reasons for the categorization of their new drug.

Pasteur Mérieux Connaught Canada, written submission

... timely sharing of information regarding on-going evaluations are of value to drug plan managers, government and consumers in general.

Alberta Blue Cross, written submission

... you do not share the information that you get from your Human Drug Advisory Panel with anybody except your staff and the members of the Board. That means that consumers and physicians are denied access to that information in terms of their ability to judge where these new products fit into the therapeutic armamentarium.

Dr. Joel Lexchin, Public Policy Hearing

... explore areas for collaboration between the PMPRB and Canadian Healthcare Association in the dissemination of information to the healthcare sector.

Canadian Healthcare Association, written submission

Pharmacists are in a key spot for communicating to the public, and we would be willing to work with you in this area of providing greater understanding to the public on this rather confusing area.

Mr. Leroy Fevang, Canadian Pharmacist Association, written submission

The Canadian Diabetes Association sees that the PMPRB's interest in serving the consumer can be significantly advanced with a stronger liaison with organizations such as the CDA.

Canadian Diabetes Association, written submission

c) Transparency in the Scientific and Price Review Process

Many stakeholders were interested in increased transparency in the scientific and price review policies and procedures. Some industry stakeholders had concerns regarding the Human Drug Advisory Panel. They believed that the scientific expertise of the panel alone may not be adequate to sufficiently review a new drug and, in particular, new biopharmaceutical products. It was felt that an expanded use of specialists might be one way to address this issue.

The Board's scientific review system operates in secret. Patentees have no access to the review conducted by the Human Drug Advisory Panel, nor does the panel have access to the patentees' scientific experts.

Mr. David Martin, Pharmacia & Upjohn and PMAC, Public Policy Hearing

The patentee experts should have the opportunity to explain the benefits of their drug to the people making the pricing decisions, rather than having to go through layers of bureaucracy. These meetings need to take place in a timely manner.

Astra Canada, written submission

If the PMPRB is to be more accountable to stakeholders, the bench marking process should be made transparent. It is difficult to evaluate the effectiveness of the board without fully knowing the information that was used to make the decision.

B.C. Pharmacare, written submission

The Board could make the price review process more transparent for consumers by providing some examples (using publicly available information) rather than just describing the guidelines in a technical manner.

BIOTECanada, written submission

d) Increased Consultations

Linked closely with the suggestions for more transparency were suggestions for broader and more frequent consultations.

CDA strongly endorses the creation of a working group to assist the PMPRB, and to make recommendations to it, with respect to matters affecting terminology or other issues surrounding the discussion of drug prices and costs.

Canadian Diabetes Association, written submission

As a payer we seek to be more involved in this current Board price review process and we encourage that you examine this method. I encourage you to consider formal input from players in your price review process in order to incorporate this very important perspective.

Hon. Clay Serby, Minister of Health, Saskatchewan, Public Policy Hearing

A consultation process which fosters open discussion among the stakeholders rather than depending on written submissions will allow all parties the opportunity to respond to the various positions put forward.

Pharmaceutical Manufacturer's Association of Canada, written submission

Stakeholders have identified that they want to be consulted on the range of issues before the PMPRB. Many stakeholders want to play a more active role in the price review process including decisions on categorization, selection of appropriate comparators and the calculation of maximum

excessive prices. In addition, stakeholders want to be involved in proposed changes to Guidelines and policy as well as the research agenda.

> ... public views on the technical aspects of pricing should also be solicited by the Board.
> *Canadian Association of Retired Persons, written submission*

> An effective process which involves stakeholders in identifying and setting appropriate comparable products for the MNE [i.e., for determining the maximum non-excessive price under the guidelines] should be explored.
> *B.C. Pharmacare, written submission*

> Provincial input is required in the determination of the category of drugs.
> *Ontario Ministry of Health, written submission*

> To increase the transparency of the PMPRB decision-making process, it would be beneficial to establish an open consultation and clarification process among the advisory experts, the PMPRB and the pharmaceutical manufacturers who could provide specialized information and resources.
> ... response to pricing submissions in a more timely manner.
> *SmithKline Beecham, written submission*

e) The Price Review Process and Guidelines

The preceding sections dealt with issues related to the transparency of the processes and methodologies adopted by the PMPRB to carry out its mandate. This section covers submissions by stakeholders which relate to the implementation of the processes and methodologies as set out in the Guidelines.

The price review process, including the categorization of medicines, was mentioned by many stakeholders as an area for possible improvement.

Some industry stakeholders, in particular, expressed concerns about the time involved in some new drug price reviews.

> The key question for us, then, looking towards that future of increasing product introductions is whether the Board's scientific review process as it now stands will be capable of dealing expeditiously and fairly with an accelerating flow of new pharmaceutical treatments.
> *Mr. Peter Kaldas, Glaxo Wellcome, Public Policy Hearing*

> The Board should establish clear time limits for responding to patentees that request advisory assistance and for reviewing introductory prices of new medicines.
> *Palmer D'Angelo Consulting Inc., written submission*

Some industry stakeholders felt that in order to fully recognize the drug innovation process, consideration should be given to amending the Guidelines to limit introductory prices for category 2 new medicines, i.e., breakthrough and substantial improvement drugs, to the range of foreign prices as opposed to the median international price. Others were concerned with the weight given to foreign prices in reviewing category 2 medicines, and felt that the prices should reflect some element of value. (See following section, "Pharmacoeconomics".) The majority of stakeholders supported the notion that the criteria used to establish price limits for non-breakthrough drugs, category 3, should be reconsidered.

> It may also be appropriate to consider a system of categorization which includes four or more categories.
>
> *Mr. David Martin, Pharmacia & Upjohn and PMAC, Public Policy Hearing*

> The PMPRB should review post marketing surveillance data to ensure that initial classification of drugs (i.e. category 2) is valid.
>
> *B.C. Pharmacare, written submission*

> The ATC classification system is not directly applicable to biopharmaceutical products ... we need a bit more flexibility in the breakthrough/substantial improvement class because of the nature of biopharmaceuticals and the fact that the field is changing so rapidly.
>
> *Mr. Reza Yaccob, BIOTECanada, Public Policy Hearing*

> Category 2 new medicines should be priced within the range of international prices ... unrealistic and unjustifiable threshold for Category 2 classification of important new medicines.
>
> *Glaxo Wellcome, written submission*

> Future consultations should reconsider the factors used to set prices for category 3 drugs.
>
> *Saskatchewan Health, written submission*

A number of stakeholders called for a review of the way the Guidelines are applied to veterinary and non-prescription, or over-the-counter, drugs.

> The animal health industry is very different from the human health industry in many respects, requiring that it be treated differently in policy and other matters.
>
> *Canadian Animal Health Institute, written submission*

> We do not believe it was originally specifically intended that non-prescription medicines be included in the same PMPRB framework as the prescription medicines, ... the dynamics in the non-prescription drug market are significantly different than the prescription drug market.
>
> *Mr. Peter Cummins, McNeil Consumer Products, Public Policy Hearing*

Some stakeholders called for a more vigorous verification of international prices.

> [We] would expect that agreements with similar entities in other countries or professional associations could provide current prices on a specific list of medications in various therapeutic categories. Failing this, there should be a mechanism allowing the PMPRB to proceed, at regular intervals such as every three years, with on-site verifications of the prices of medications. The PMPRB could also in certain cases enlist the assistance of wholesalers or pharmacy associations in various countries to confirm the prices of medications.
>
> *Canadian Pharmacists Association, written submission*

There were also suggestions regarding alternate uses for the funds obtained under voluntary compliance undertakings.

> ... changing the "return of funds" process so that funds are returned to the purchasers. These funds should be returned to the purchasers i.e., to provincial health budgets, or alternatively to agreed upon national health initiatives; thus making the PMPRB's role in consumer protection more evident.
>
> *Canadian Healthcare Association, written submission*

f) Pharmacoeconomics

Many stakeholders supported the useful role that pharmacoeconomic analysis could play in the price review process. There was, however, no clear view on how such analysis could be incorporated and some believed that it should not become a mandatory requirement. There was general agreement that it would be important to establish guidelines for any use of pharmacoeconomic analysis.

> The price of a product should bear a relationship with the benefit derived from the product.
>
> *Saskatchewan Health, written submission*

> In addition to the international median price another criterion should be the value that the drug offers. The initial and subsequent determinations may need to consider the pharmacoeconomic studies done by the manufacturers and independent organizations such as CCOHTA.
>
> *Green Shield, written submission*

Pharmacoeconomic evaluations should play an important role within the introductory price reviews if they are objectively and independently conducted.

Canadian Society of Hospital Pharmacists, written submission

...the use of economic evaluations in the establishment of prices for patented medicines merits attention. ... We feel that the establishment of guidelines as to the utilisation of economic evaluations within the price evaluation process is necessary. To that end, a committee of experts should be gathered.

Sauriol, Côté & Barbeau, Université Laval, written submission

The Board should develop clear guidelines to the application and interpretation of pharmacoeconomic data.

Brogan Inc., written submission

The Board should limit its use of pharmacoeconomic information to cases where a standard therapeutic class comparison alone is not adequate or appropriate.

Pharmaceutical Manufacturer's Association of Canada, written submission

g) Next Steps

The Board has appreciated the thoughtful and substantive comments made by stakeholders in response to the questions raised in the Discussion Paper. The matters described in this section are matters within the jurisdiction of the Board and this input will be used in charting the way ahead.

We have relied heavily on the submissions from stakeholders to develop the action plan which is set out in the following section.

5. ACTION PLAN FOR FOLLOW-UP ON ISSUES RAISED BY STAKEHOLDERS

The Board has benefitted from the interaction with its stakeholders. These consultations have facilitated the identification of new stakeholders and strengthened our contact with others. A direct result of this consultation process will be a change in the way the PMPRB interacts with its stakeholders.

All of the issues raised by stakeholders cannot be addressed at the same time. For a number of issues, work was already in progress at the time of our consultations. The action plan in this report, and the documents which accompany it, are a result of the consultation process; they address many of the issues raised by stakeholders that are within the Board's jurisdiction. The research agenda described below has been developed to keep stakeholders informed about work underway and matters that we plan to work on at a later point.

We welcome feedback from stakeholders on the action plan and research agenda.

A first step in changing the way the Board does business will be in the formalization of a consultation policy. This policy is a commitment by the Board to reach out to its stakeholders on issues that they have raised, and to systematically seek their input in identifying solutions.

a) A Consultation Policy

The Board is announcing a new Consultation Policy ...

To generate public confidence and trust requires an effective framework that commands public support. The implementation of such a framework must ensure that the views of stakeholders have been heard and been appropriately considered in the policy formulation process.

The Board is announcing a new Consultation Policy which is attached to this report.

This Consultation Policy will shape the Board's initiatives, but it is not etched in stone. The Board will always welcome suggestions about ways to improve and build on that framework.

The Board wants to facilitate and assist Canadians to participate in its consultations. Consultation involves obligations. It involves a commitment on the part of all participants to listen and to communicate their ideas as clearly as possible. It involves a commitment by the Board to share information and communicate with all stakeholders.

Many stakeholders perceive that they are not equally balanced in terms of resources or influence in the process. The Board continues to be determined to make every effort to ensure that all interested parties have an opportunity to get their messages across and will consider these messages during its deliberations. The Board will do this by adopting a variety of communication tools and by finding new and creative ways to share information with its range of stakeholders.

b) Stakeholders Meeting

... the Board will hold its first Stakeholders Meeting on November 20, 1998.

In response to the recommendation of many stakeholders, and consistent with the new Consultation Policy, ***the Board will hold its first Stakeholders Meeting on November 20, 1998***. Invitations to the major stakeholder organizations will be sent out early in the fall.

The Stakeholders Meeting will provide an important vehicle for the Board to receive feedback on this report and other issues, including the anticipated report of the Auditor General of Canada this fall. We will also be inviting feedback on the Research Agenda and seeking participation and assistance in the specific issues under further consultation.

Notices of stakeholders meetings will be published in the NEWSletter and on our website and the minutes and other documents related to those meetings will be available on the public record.

c) Research Agenda

The Board is publishing its Research Agenda.

The consultation process gave the Board the opportunity to ask stakeholders whether the PMPRB should consult on its research agenda. Overwhelmingly, the Board heard that stakeholders would like to be consulted in this way. It was felt that the opportunity to have input into the PMPRB's research agenda would be useful and beneficial.

> It would also be very valuable to the public to know about your research agenda and methods in clear, simple and non-technical language.
>
> *Canadian Association of Retired Persons, written submission*

The Board is therefore attaching to this report its first Research Agenda. This agenda sets out issues identified either by stakeholders or the Board which require further research and analysis. The agenda also outlines those areas where the Board is consulting, or plans to consult, with stakeholders on matters that may result in adjustments to its policies and procedures.

The Research Agenda will be a tool to facilitate the establishment of priorities taking into account the views of stakeholders.

This agenda is not intended to be a static document. It will form part of the PMPRB's annual planning process and will determine our areas of priority for the next year. The publication of the Research Agenda will become a yearly event. The Board welcomes all suggestions.

d) Communications

The Board recognizes the importance of communicating with stakeholders and the role it will play in future consultations. The Board will continue to inform stakeholders of its role in the health care system but will do so with particular emphasis on:

- fostering greater awareness among consumers of its on-going compliance, research and administrative activities.
- facilitating and encouraging a two-way exchange of information.

toll-free : **1-877-861-2350**

One way in which the Board will seek to reach consumers is through the development and consolidation of a network of partners in the health services community. Partnerships for the exchange of information will permit the Board to reach a broader range of consumers. The Board will follow up on the interest expressed by a number of stakeholders during the consultation process to create partnerships for the dissemination of information.

A variety of tools have and will be used to facilitate two-way communication with our stakeholders. Some of these include:

- the toll-free telephone line was set up during the consultation process
- an expanded website that has interactive features permit greater direct exchanges with stakeholders
- exploring linkages to other networks (e.g., Canadian Healthcare Association, Canadian Diabetes Association, Canadian Association of Retired Persons, Canadian Pharmacists Association and Canadian Society of Hospital Pharmacists)
- publishing summaries of Board meetings
- more frequent NEWSletters
- exploring other ways to reach consumers, such as general and issue-specific information brochures.

http://www.pmprb-cepmb.gc.ca

The communication process is intended to facilitate and encourage an ongoing exchange of information. This process is adaptable to respond to the needs of stakeholders. Feedback from stakeholders will be a key determinant in knowing whether a particular tool fulfills its objective or whether another might be more appropriate; and whether the information provided meets stakeholder requirements.

e) Information

During the public information sessions held across Canada, the message regarding information was fairly consistent. Consumers feel confused as they hear conflicting reports and, consequently, do not believe much of the information they hear. They often feel that not enough information is being made available, or that it is not being made available in a timely manner.

The PMPRB will continue to seek to identify and respond to the information needs of interested parties.

As previously stated, stakeholders have expressed a clear desire to become more involved in the Board's activities. This will require that appropriate information be made available in order to permit stakeholders to be in a position to better participate and make a contribution. In future communications, the Board will seek to use non-traditional ways to communicate its messages and make more use of "plain English".

> If you cannot get your message to the consumers and make them understand, you will never succeed.
> *Mr. Ken Maybee, New Brunswick Lung Association*

> How can the public challenge the high prices of pharmaceuticals if they do not understand how they are arrived at. ... give the public an opportunity to debate the issue.
> *Mr. Al Cerelli, Congress of Union Retirees of Canada*

During this consultation process stakeholders were asked to identify additional information they would like to receive. The Board received suggestions from a number of stakeholders dealing with information relating to the price review process, research and development and drug pricing and costs.

There is some information the Board receives that must be treated as confidential under the law, but most of the information identified by stakeholders does not fall within that category. The Board can put out more information on its reviews of new drugs and can also report confidential sales information in an aggregate form. The Research Agenda outlines how we plan to address these requests. However, some of the information requested by stakeholders is not currently collected by, or accessible to the PMPRB; for example, a breakdown of drug costs by province or information on drug utilization patterns. Nevertheless, the Board will seek to enhance its reports to address some of the suggestions made by stakeholders (e.g., creating a price or cost index for particular disease groups).

Information is a component of all activities carried out by the PMPRB and how this information is shared with stakeholders is a key determinant to involving stakeholders in upcoming consultations. As outlined in the Research Agenda, the Board will be consulting on changes to its scientific and price review policies and methodologies. As appropriate, these consultations will also address the most appropriate way to provide the information stakeholders have requested.

As part of the price review process for new patented drugs discussed below, the PMPRB is proposing to publish on its website and in the NEWSletter, starting in the fall 1998, an updated list of new patented medicines which are under review.

f) Trends in Patented Drug Prices and Expenditures

Stakeholders need the most up-to-date facts regarding the pricing and expenditure trends of patented drugs sold in Canada. It is necessary to have the complete picture in order to fully participate in upcoming consultations, and to be in a better position to contribute constructively in reviewing proposals for changes to policy and guidelines.

The Board is therefore releasing the attached report entitled "Trends in Patented Drug Prices" (S-9811). It is a comprehensive report providing up-to-date information on drug pricing and expenditures, including pricing data by drug category.

The Board is releasing a report on "Trends in Patented Drug Prices."

During the consultation process, many stakeholders were concerned that introductory drug prices were too high. There was also concern regarding the highest price international price comparison rule, in particular in the case where the drug product was being sold in fewer than five comparator countries. The attached report provides factual information regarding drug pricing and provides details of the frequency of cases where there were fewer than five comparator countries.

The Board hopes that this report will provide all stakeholders with additional and up-to-date factual information to form the basis of future examinations of pricing methods and guidelines.

Some interesting facts coming out of the report:

- In 1997, worldwide sales of drugs have been estimated to be more than $400 billion, an increase of 8.6% from 1996. In Canada, total sales of drugs increased by about the same rate, 7.0%, to an estimated $7 billion.
- But sales of patented drugs in Canada increased at a much faster rate in 1997, by almost 23% to $3.7 billion. For the first time, patented drugs accounted for over half of manufacturers' sales of all drugs in 1997.
- New drugs introduced in the last decade represented 89% of all sales of patented drugs in 1997.
- In 1997, 78% of patented drug products were priced below the median international price in Canada; in 1987, only 45% were priced below the median international price.
- By 1997, prices for patented drugs in Canada had come down relative to the seven other countries in the basket. In 1987, Canada had the highest price in over 21% of the cases, but this had dropped to less than 2% of the cases in 1997.

g) Verification of Foreign Patented Drug Prices

The Board has prepared a report on the "Verification of Foreign Patented Drug Prices."

Questions concerning the reliability of the foreign price information used by the Board arose during the review of Bill C-91 in 1997, and the Board sought input from stakeholders on this question in its Discussion Paper.

The Board believes it important to use the best information possible and that the public have confidence that it is doing so. To these ends, we have undertaken a thorough review of sources of foreign price information and ***the Board has prepared the attached report, "Verification of Foreign Patented Drug Prices" (S-9812)***.

This report provides details on price information available in other countries and the ways in which we can verify information filed by drug companies. The "Verification" report explains how public price information for the European countries in our basket can be used to check the prices filed by companies. The foreign formularies and publications showing prices can be examined at our offices. In addition, more information is becoming available through the internet, for example:

- U.S. Department of Veterans Affairs: http://www.dppm.med.va.gov

In terms of international price comparisons, a number of stakeholders had concerns regarding the United States as one of the comparator countries.

> Drug prices in the U.S., for example, are among the highest in the world. ... the result is to skew subsequent price comparisons by the PMPRB.
>
> *Mr. Rodney Kort, Canadian AIDS Society, Public Policy Hearing*

> ... to include the U.S., where there is no attempt to control prices, we feel distorts that calculation.
>
> *Ms. Jean Jones, Consumers Association of Canada, Public Policy Hearing*

The "Verification" report does not address price information for the United States. "Ex-factory", or manufacturers', prices for patented drugs cannot be derived as readily from publicly available sources in that country. Pharmaceutical prices in the United States are not regulated except under special circumstances.

Given the concerns of some stakeholders and based on its unique situation, the issue of U.S. pricing will be the subject of a separate study. The first phase of this study will examine the Department of Veterans' Affairs formulary.

h) U.S. Prices: Department of Veterans Affairs Formulary

The Board is releasing a paper on "U.S. Prices: Department of Veterans Affairs Formulary."

Throughout the consultation process, some stakeholders took issue with the Board's international price comparisons and, in particular, the use of high priced countries. The Board indicated that it is not within its mandate to exclude any country for its price comparisons. However, the Board does have to ensure that the prices that are filed with the Board are reliable. As part of its "Verification" study, and other research prompted by stories in the media, the Board became aware of a new source of price information in the U.S. that recently became publicly available in November 1997. These prices are for drug products sold to the Department of Veterans Affairs (DVA) and certain other federal agencies.

The Board has prepared the attached paper "U.S. Prices: Department of Veterans Affairs Formulary."

The *Patented Medicines Regulations* require patentees to submit information on the publicly available ex-factory price for medicines that are sold in one or more of the specified countries.

The Board is of the view that patentees should begin filing information on publicly available prices to the U.S. government under the *Patented Medicines Regulations* effective as of the next regular filing date,

January 30, 1999. With the publication of the paper, we are providing patentees and other stakeholders an opportunity to propose options as to how that information should be used for future comparisons.

i) Price Review Process for New Patented Drugs

During the Board's recent consultations, stakeholders expressed concerns regarding the transparency and timeliness of the price review of patented medicines. We have listened to stakeholders and are committed to make changes to:

- make the price review process more open and transparent to all stakeholders;
- improve the efficiency and timeliness of the process; and,
- maintain a high level of quality in the assessments made by Board staff.

To begin the process of change, the PMPRB will issue a discussion paper this fall on the process to review the prices of patented medicines.

Most comments received during the consultation concerned the review of the introductory prices of new patented medicines. The paper will, therefore, focus on the PMPRB's review of new drug products.

The Board will be consulting on:

"Price Review Process: Preliminary Outline of Issue"

The Board also intends to form a working group that will review the discussion paper and make recommendations for the Board to consider on changes to the price review process. The composition of the working group, which will include representatives of the Board's various stakeholder groups, will be announced following the Stakeholders Meeting in November 1998. It is hoped that the first meeting of this working group will be held in early 1999.

The attached paper, "Price Review Process: Preliminary Outline of Issues" is intended to give notice of the issues to be addressed in the Discussion Paper and considered by the working group. If you have any comments or are interested in participating in the working group, please contact the Secretary of the Board.

j) Category 3 Drug Prices

and on:

"Category 3 Drug Prices: Preliminary Outline of Issues"

During the consultations, many stakeholders made submissions regarding the pricing of category 3 new drugs. There was general agreement that the criteria used by the PMPRB for establishing maximum non-excessive prices requires re-examination. Payers believe this to be necessary to ensure that Canadians are receiving good "value" when these drugs are introduced. Industry stakeholders argued that the Guidelines are too restrictive and do not allow moderate improvement drugs a price premium over existing drug therapies.

In response to these concerns, the PMPRB proposes to consult further on specific issues. Among other things, the paper:

1) provides additional details on the current methodology followed by the Board in order to make the operation more transparent;
2) assists interested parties to better prepare to make specific suggestions for change; and,
3) solicits more feedback from stakeholders on ways that the methodology can be improved; and
4) provides three case studies.

To encourage stakeholders to begin thinking about the issues involved we are *today releasing a paper, "Category 3 Drug Prices: Preliminary Outline of Issues".*

The working group being established to consider the price review process for new patented drugs will also be asked to consider the PMPRB's price review methodology for category 3 drugs. If you have any comments or are interested in participating in the working group described in the previous section, please contact the Secretary of the Board.

During the consultations the Board also sought and received submissions on other issues related to the Guidelines. Further information on some of these questions, e.g., the instances of fewer than seven countries in an international comparison, is contained in the "Price Trends in Patented Drug Prices" report. These issues are identified for future work on the Research Agenda.

k) Patented Veterinary Medicine Prices

... the Board is publishing a proposal, for Notice and Comment, to modify its approach to the regulation on veterinary drug prices.

Stakeholders agree that the priority for the Board must continue to be drugs for human use. The Board would like to streamline its regulation of veterinary drugs to ensure that focus.

Therefore, the Board is publishing a proposal, for Notice and Comment, to modify its approach to the regulation on veterinary drug prices.

The attached report "Notice and Comment: Regulating Patented Veterinary Medicine Prices" sets out in detail how the Board proposes to deal with veterinary drug products.

With this report, the Board is beginning formal consultation on its proposal by way of Notice and Comment. Interested stakeholders are being asked to provide written comments to the Secretary of the Board **by November 20, 1998**.

Once all comments received have been considered, and if the Board is satisfied that it should proceed with its proposal, the new process would become effective in January 1999.

6. CONCLUSION

Our year-long consultations on the role, function and methods of the PMPRB have been challenging and rewarding. We have had the opportunity to travel the country and to meet with many Canadians from different walks of life. We have been impressed by the quality of submissions that we have heard and by the commitment of so many individuals and organizations.

There continues to be a wide disparity in the views of Canadians about the Government's drug patent policies and we believe we heard most of them. As promised, we have tried to communicate those concerns to the Government through this report.

We also heard many different views about how the Board should fulfill its mandate. As promised, we have set out a plan of action, our ***Road Map for the Next Decade***, to attempt to address those concerns and suggestions.

Although there are many conflicting views among our stakeholders about Canada's drug patent policies and the appropriate role and function of the Patented Medicine Prices Review Board, we are encouraged by how much they have in common, including: a commitment to maintaining and improving Canada's health care system and a recognition of the importance of the appropriate use of pharmaceuticals in health care. We appreciate, and share, the commitment of our stakeholders to work together in helping us fulfill our mandate to protect Canadian consumers by ensuring that the prices charged by manufacturers of patented medicines are not excessive.

APPENDICES

A. Regional Information Sessions

B. Written Submissions

C. Appearances at the Public Policy Hearing, April 30 – May 1, 1998

PMPRB - CONSULTATION SCHEDULE
1997 - 1998

DISCUSSION PAPER	*November 26, 1997*
Public Sessions/Rencontres publiques	
	February / Février
Winnipeg	***2***
Regina	***3***
Edmonton	***4***
Yellowknife	***5***
Vancouver	***10***
Whitehorse	***12***
Fredericton	***16***
Halifax	***17***
St.John's	***18***
Charlottetown	***19***
	March / Mars
Montréal	***3***
Toronto	***4***
Ottawa	***5***
Time **7:00 p.m.** to 9:00 p.m. **Venue** Will also be announced in the Saturday newspapers	
Written Submissions	*by March 31, 1998*
Public Hearing	*Ottawa - April 30, 1998*
Interim Progress Report	*May 22, 1998*
Release of the Board Report	*Late Summer 1998*

CEPMB - HORAIRE DE CONSULTATION
1997 - 1998

DOCUMENT DE DISCUSSION	*26 novembre 1997*
Locations/Endroits	
Delta Winnipeg	*288 Portage Avenue*
Hotel Saskatchewan Radisson Plaza	*2125 Victoria Avenue*
Delta Edmonton Centre Suite Hotel	*10222 - 102 Street*
The Explorer	*48th Street & 49th Avenue*
Aquarium	*Stanley Park*
Westmark Whitehorse	*Second and Wood Street*
Sheraton Inn	*225 Woodstock Road*
Citadel Halifax	*1960 Brunswick Street*
Delta St.John's	*120 New Gower Street*
The Prince Edward	*18 Queen Street*
Delta Montréal	*475 President Kennedy*
Delta Chelsea Inn	*33 Gerrard West / ouest*
Centre Standard Life Centre	*333 Laurier West / ouest*
Heure **19h** - 21h **Endroit** Sera également annoncé dans les journaux du samedi	
Présentations écrites	jusqu'au *31 mars 1998*
Audience publique	*Ottawa - 30 avril 1998*
Rapport d'étape	*22 mai 1998*
Publication du rapport du Conseil	*été 1998*

Patented Medicine
Prices Review Board

CANADA

Consiel d'examen du prix
des médicaments brevetés

SUBMISSIONS ON THE PMPRB'S DISCUSSION PAPER

Examining the Role, Functions and Methods of the Patented Medicine Prices Review Board

1. Aids Action Now!
2. Alberta Blue Cross
3. Allelix Biopharmaceuticals
4. Aslam H. Anis, Ph.D. - Pharmacoeconomic Initiative of British Columbia
5. Astra Canada
6. John A. Bachynsky, Ph.D. - Faculty of Pharmacy and Pharmaceutical Sciences Alberta University
7. BIOTECanada
8. Boehringer Ingelheim (Canada) Ltd./Ltée
9. Bristol-Myers Squibb Pharmaceutical Group
10. British Columbia - Ministry of Health
11. Brogan Inc.
12. Canadian Aids Society
13. Canadian Animal Health Institute
14. Canadian Association of Retired Persons
15. Canadian Cosmetic, Toiletry and Fragrance Association
16. Canadian Cystic Fibrosis Foundation
17. Canadian Diabetes Association
18. Canadian Drug Manufacturers Association
19. Canadian Healthcare Association
20. Canadian Pharmacists Association
21. Canadian Nurses Association
22. Canadian Society of Hospital Pharmacists
23. Coalition sur l'Assurance-médicaments au Québec
24. Congress of Union Retirees of Canada
25. Consumers' Association of Canada
26. Council of Senior Citizens Organizations of British Columbia
27. Eli Lilly Canada Inc.

12h00		Green Shield - Vern Chiles
12h30		Break / Pause
13h30		PMAC / ACIM - Judy Erola, Nelson Sims (Eli Lilly) David Martin (Pharmacia & Upjohn)
14h00		Dr. Joel Lexchin
14h30	Panel	Patentees / Brevetés Boehringer Ingelheim - Betsy Miller Glaxo Wellcome Inc. - Rob Last, Peter Kaldas Merck Frosst - Phillipe Hébert, Vladimir Perocevic, Rob Livingstone
15h30		Health break / Pause santé
16h00		The Honourable / L'honorable Clay Serby Minister of Health / Ministre de la santé, Saskatchewan
16h30		Canadian Animal Health Institute / L'institut canadien de la santé animale - Charlotte Foster, Dr Myron Roth & Kevin Grier

Friday, May 1 / vendredi 1er mai 1998

8h30	Panel	BioteCanada - Reza Yacoob Pasteur Mérieux Connaught - Dr. Thomas E. Hassell Allelix Biopharmaceuticals Inc. - Douglas Froom
9h30		Canadian Pharmacists Association / Association des pharmaciens du Canada - Leroy Fevang & Noëlle Dominique Willems
10h00		Nonprescription Drug Manufacturer's Association of Canada / Association canadienne de l'industrie des médicaments en vente libre - Gerry Harrington & Peter J. Cummins
10h30		Health break / Pause santé
10h45		Consumers Association of Canada / Association des consommateurs du Canada - Jean Jones
11h15		Canadian Drug Manufacturers' Association / Association Canadienne des Fabricants de Produits Pharmaceutiques - Brenda Drinkwalter & Jim Keon
11h45	Panel	Pivotal Drug Consultants Inc. - Dr Gordon Johnson Palmer D'Angelo Consulting Inc. - W. Neil Palmer

---

For information on simultaneous translation, transcription of proceedings and the Public Record, please contact the Secretary to the Board at (613) 954-8299.

Pour de plus amples renseignements sur la traduction simultanée, la transcription des échanges et le dossier public, veuillez communiquer avec la Secrétaire du Conseil au (613) 954-8299.

[Attachment to the *Road Map for the Next Decade*]

I. POLICY

The Patented Medicine Prices Review Board (PMPRB) is committed to consult on the way it conducts its business and on opportunities to improve both its operations and its relations with stakeholders.

This Consultation Policy is designed to reflect the values of transparency and public accountability and to encourage and facilitate input from all stakeholders.

II. PURPOSE

To establish a framework, guiding principles, and service standards to govern public consultations by the Patented Medicine Prices Review Board.

III. BACKGROUND

The Board has traditionally consulted on major aspects of its operations such as the Guidelines on excessive price and patent dedication. These consultations have taken many forms: written comments by way of Notice and Comment, the Bulletin, informal exchanges, public hearings, a working group in the case of the amendments to the Guidelines in 1993, questionnaires, bulletin boards and conferences.

The Board's approach is consistent with the Government's policy on consultation (December 1992), which states "... it is the policy of the Government of Canada to pursue and to promote consultation with Canadians in the development of public policy and in the design of programs and services."

Nonetheless, the Board has a low public profile and some stakeholders have not seen it as being open to consultation. In its report in 1997, the Standing Committee on Industry noted that "... many witnesses wanted [the PMPRB] to fulfill a wider role in a more publicly responsive way..." and recommended to the government that its mandate be reviewed and strengthened. It also recommended that the Board consult on its reporting activities.

In mid-1997, the Board embarked on a comprehensive review and renewal process examining a range of issues. The Board initiated a broad consultation with its stakeholders in late 1997 to examine its role, functions and methods with a view to being more relevant to the needs of those it serves. The results of this consultation process confirmed the desire of stakeholders that the Board consult on a regular basis.

IV. STATUTORY PROVISIONS

Under paragraph 96(5) of the Patent Act, the Board, before issuing any guidelines, "shall consult with the Minister (of Health Canada), the provincial ministers of the Crown responsible for health and such representatives of consumer groups and representatives of the pharmaceutical industry as the Minister may designate for the purpose."

In addition, the Act provides that the Minister shall consult with stakeholders before recommending regulations regarding additional price determination factors, definitions of "research and development" and additional powers and duties of the Board.

In carrying out its quasi-judicial functions, i.e., in determining if a price is excessive and ordering remedial action, the Board is required to apply the rules of natural justice and ensure the patentee has a right to be heard. Hearings are conducted in public. Ministers of health of the provinces and the Minister of Industry Canada have standing to appear and make representations in all hearings and the Board's rules permit other parties who demonstrate an interest in the matter to intervene.

V. OUR APPROACH TO CONSULTATION

The Board considers consultation an important part of the way it does business. Effective consultation should ensure that stakeholders are aware of and have opportunities to comment on activities that may affect them. Such an approach supports an open and transparent decision-making process which allows for meaningful public input.

In addition to the principles of openness and transparency, effective consultations are based on integrity and mutual respect. Consultation is a key part of the Board's operations and requires good planning, research, analysis, advice, feedback and an ongoing commitment of human and financial resources.

VI. THE OBJECTIVES OF CONSULTATION

- to facilitate input and feedback from stakeholders and the public on the Board's activities.
- to ensure that the Board is able to consider the views of all stakeholders in making policy decisions.
- to facilitate an ongoing exchange of information and feedback among the Board, its stakeholders and the public.

VII. GUIDING PRINCIPLES

The following principles will be applied to the Board's consultations.

- *Building relationships and trust:*
  The PMPRB, as a fundamental part of its operational focus, consults on a regular basis with its stakeholders. To give effect to this, the PMPRB must therefore not only consult but also be seen to consult.

- *Enhancing openness:*
  The PMPRB's consultation activities reflect transparency and accountability through inclusiveness, accessibility, consistency of message and process, and feedback.

- *Ensuring an effective process:*
  Establishing clear roles and responsibilities is critical to effective consultations. A solid, mutual understanding of the issues, objectives, purpose and expectations of all parties is also essential. To facilitate consultations, the PMPRB is committed to the service standards set out below.

- *Linking consultation and operation planning:*
  The results of the consultations will be integrated through the Research Agenda into the planning process of the Board in terms of strategic and operational considerations and the development of future consultation plans.

- *Adhering to high quality and performance standards:*
  As part of the evaluation process, the PMPRB is committed to a continuous review of its consultative efforts and to assess, based on current best practices, opportunities to enhance its consultations.

VIII. SERVICE STANDARDS

- The Board will maintain and publish an annual Research Agenda as part of its annual planning process. Among other things, the Research Agenda will identify initiatives that are currently, or may become, subject to public consultations.

- The Board's consultation plans will allow sufficient preparation time for meaningful participation by stakeholders.

- For each consultation initiative, the Board will develop a plan including these elements:

  – Identify the objectives of the specific consultation.

  – Develop an action plan setting out roles and responsibilities, both internally and with stakeholder participants.

  – Ensure that the values, interests, knowledge and contribution of participants are considered.

  – Identify in advance what information will be needed to support the consultation process and how this will be shared with stakeholders.

  – Determine how communications will be managed before, during and after the consultation process.

  – Identify evaluation and feed-back mechanisms.

- Consultations shall be conducted in a public manner. For each consultation initiative, the Board will ensure that all written submissions and minutes of meetings with stakeholders as well as summaries of minutes of working groups and task forces are placed on the public record and reported on the website.

- Progress reports and the results of the consultations will be shared with stakeholders in a timely fashion and summarized in the Annual Report, the NEWSletter, the website, and in other ways as appropriate.

IX. METHODS OF CONSULTATION

To facilitate consultations with the various stakeholders and to promote accessibility and transparency, the Board will draw on a range of mechanisms as may be most appropriate in the circumstances. These include:

- *Discussion Paper*: an analysis or report which raises questions and invites responses, usually in writing, within established time lines.
- *Notice & Comment*: a published proposal for a change to policy or guidelines with a request for written comments within established time lines.
- *Working Groups or Task Forces*: groups of experts representing key stakeholders, ordinarily on more technical or complex issues, to report conclusions and recommendations for the Board to consider.
- *Public Policy Hearing*: a public hearing by the Board to allow stakeholders to present or explain their views directly to the Board.
- *Stakeholders Meeting*: with representatives of all major stakeholder groups to consult directly with the Board on broader issues of policy and the Research Agenda.
- *Public Meetings*: special meetings involving Board members that are open to the public (e.g., regional information sessions in 1998).

X. ENQUIRIES AND COMMENTS

Your comments should be addressed to the Secretary of the Board:

Standard Life Centre
Box L 40
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Toll-free number: 1-877-861-2350
Direct line: (613) 954-8299
Fax: (613) 952-7626
E-mail: sdupont@pmprb-cepmb.gc.ca

PMPRB Research Agenda: 1998–2000 — September 1998

Issue	Description	Advisory Committee	Key Deliverables	Date
Stakeholders Meeting	Public meeting with Board	--	--	Nov 20 1998
New Medicine Price Review Process	Price review process for new patented drugs	PMPRB Working Group on New Medicines	1. Discussion Paper 2. Working Group - 1st Meeting 3. Report	Fall 1998 Jan 1999 Fall 1999
Category 3 Drug Prices	Review the methods to conduct therapeutic class comparisons and the guidelines for category 3 drugs	PMPRB Working Group on New Medicines	1. Refer to Working Group 2. Report	Jan 1999 Fall 1999
United States Prices	The use of publicly available prices in the DVA formulary	--	1. Paper on DVA Formulary 2. Deadline for Comments 3. Effective date for Filing	Sep 1998 Oct 30 1998 Jan 1999
Regulating Veterinary Drug Prices	Proposal on an alternative approach to regulating prices of patented veterinary drugs	--	1. Notice and Comment 2. Deadline for Comments 3.Implementation	Sep 1998 Nov 20 1998 Jan 1999
Non-Patented Single Source Drug Prices	Study for F/P/T Task Force: International Price Comparison of Top Selling Non-Patented Single Source Drugs	--	Report submitted to F/P/T Task Force on Pharma-ceutical Issues	Fall 1998
Pharmaceutical Price Indices	To review drug price indices reported by Statistics Canada and PMPRB	PMPRB/ Statistics Canada Working Group	Report	Winter 1999

Issue	Description	Advisory Committee	Key Deliverables	Date
Category 2 Drug Prices	1. Review the appropriateness of the median price test for Category 2 drugs 2. Review the appropriateness of the "Highest Price Rule" 3. Review the appropriate test when fewer than 7 countries	PMPRB Working Group on New Medicines	TBA	TBA
Pharmaco-economics	The use of pharmaco-economics in drug price reviews	TBA	TBA	TBA
Regulating Non-Prescription (OTC) Patented Drug Prices	Approach to non-prescription (over the counter) patented drug prices	TBA	TBA	TBA

The PMPRB Working Group on New Medicines will be established in late fall 1998.

TBA: To be announced

Throughout the Board's recent consultations, some stakeholders took issue with its international price comparisons and, in particular, the use of high-priced countries. The Board indicated that it is not within its mandate to exclude any country from its price comparisons. However, the Board does have to ensure that it is relying on the best publicly available information.

When this issue was raised during the hearings of the Standing Committee on Industry in 1997, the Board engaged Deloitte & Touche to review the price verification process undertaken by the PMPRB. In addition, because media reports indicated that an alternate source of U.S. pricing data was not being included in the PMPRB's international price comparisons, the staff were directed to investigate this source. In April 1997, Deloitte & Touche, among other things, concluded that patentees were complying with the legislated filing requirements. The Chairperson was also able to inform the Standing Committee on Health that work was continuing in the area of foreign price verification and that a report would be published indicating the results of the review.

The alternate source of U.S. prices referred to in the media report was for drug products sold to the U.S. Department of Veterans Affairs (DVA) and certain other federal agencies. These prices became publicly available for the first time in November 1997, and they represent manufacturers', or "ex-factory", prices.

The Veterans' Health Administration provides hospital, nursing home and domiciliary care, outpatient medical and dental care for any person who has served on active duty in uniformed services for specified time periods. The DVA has responsibility for such things as compensation, pension and education benefits, medical care, hospital, cemetery and construction programs. The implementation of a national drug formulary was announced on May 9, 1997 and was made available for the first time via the Internet[1] in November 1997. The formulary covers prescription medications, over the counter drugs and medical and surgical supplies.

The DVA is said to operate one of the largest purchasing cooperatives with multi-year contracts in the U.S. and, as such, is able to negotiate contracts at discount prices. The Federal Supply Schedule (FSS) lists the pharmaceutical products and their prices which are available to federal agencies and institutions and several other purchasers, such as the District of Columbia, U.S. territorial governments and many Indian tribal governments.

The FSS contract is a multiple award, multiple year contract that provides a variety of product choices to the customers. The FSS contracts are grouped by type of pharmaceutical product.[2] The single source innovator, multiple source

---

1 For drug and pharmaceutical prices the Website address is http://www.dppm.med.va.gov

2 (1) Non-prescription medicated cosmetic & surgical soaps; (2a) single source innovator, multiple source innovator, biological & insulin pharmaceutical products; (2b) generic, multiple source pharmaceuticals and drugs, human drug products and OTCs; (3) IV delivery systems; (4) new molecular entity; (5) nutritional/dietary supplements.

innovator, biological and insulin pharmaceutical products are those products which are considered "covered products" and are included on the DVA formulary. These include the drug products that are comparable to drug products that fall within the PMPRB's jurisdiction.

The authority for negotiating prices for the covered drug prices comes from Public Law 102-585, Veterans Health Care Act (VHCA) of 1992. Section 603 of the VHCA authorizes the Veterans Affairs Secretary to negotiate prices with drug manufacturers for products that the Department of Veterans Affairs itself needs as well as what the Department of Defense, the Public Health Services (including Indian Health Service) and the Coast Guard require.

To comply with the VHCA, pharmaceutical companies must enter into agreements whereby they agree to offer all "covered drugs" to the Federal Supply Schedule (FSS) at no more than their calculated Federal Ceiling Price (FCP). In essence, however, the legislation dictates that a minimum 24% discount below the manufacturers' most favoured commercial price and terms be provided to the DVA. This price is listed on the DVA formulary as the "FSS price". In addition, the DVA formulary lists three other prices for smaller groups of covered drugs which may have discounts greater than the FSS discount of 24%.

By way of example, the drug product Zocor (simvastatin) 20 mg tablets sold in packages of 60 by Merck Frosst Inc. in Canada, is listed in the DVA formulary at the FSS price of $91.98 U.S. The Redbook[3] lists the direct price to retail pharmacies in that country at $169.87 U.S. In Ontario, the Ontario Drug Benefit Formulary lists the drug at the price of $2.20 per tablet (or $132.00 for 60 tablets). Using the Board's 36 month exchange rate to convert the U.S. prices to $Canadian, the Canadian price of $132.00 is slightly higher than the DVA converted price of approximately $125.00, but lower than the direct price of $232.25 from the Redbook.

Patented Medicines Regulations

Section 4(1)(g) of the Regulations requires that when a patented drug is sold in Canada, the patentee must file the publicly available ex-factory price for each dosage form, strength and package size for each class of customer in each of the countries listed in the Regulations.

"Publicly available ex-factory price" is defined in section 4(10) of the Regulations as including any price of a patented medicine that is agreed on by the patentee and the appropriate regulatory authority of the country in which the medicine is sold by the patentee.

---

[3] The Redbook, published by Medical Economics Data Production Company in the United States, provides average wholesale prices (prices pharmacists will pay to the wholesaler) and direct prices (prices the pharmacist will pay to the manufacturer when purchasing directly).

The Board is of the view that prices charged by patentees to the U.S. DVA, as reported in the formulary, should be filed with the Board under the Regulations along with the other foreign prices filed. The next regulatory filing deadline is January 30, 1999, for the period July 1998 through December 1998.

The Board is examining the appropriate ways in which this information should be taken into account in conducting international price comparisons and it invites the views of stakeholders. **Stakeholders are requested to provide their comments in writing to the PMPRB by October 30, 1998.**

COMMENTS

Your comments should be addressed to the Secretary of the Board:

Standard Life Centre
Box L 40
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Toll-free number: 1-877-861-2350
Direct line: (613) 954-8299
Fax: (613) 952-7626
E-mail: sdupont@pmprb-cepmb.gc.ca

[Attachment to the *Road Map for the Next Decade*]

INTRODUCTION

During the Board's recent consultations, a number of stakeholders expressed concerns regarding the transparency and timeliness of the PMPRB's price review of patented medicines. The Board has listened to:

- make the price review process more open and transparent to all stakeholders;
- improve the efficiency and timeliness of the process; and,
- maintain a high level of quality in the assessments made by Board staff.

To begin the process of change, the PMPRB is preparing a discussion paper on the price review process. The paper will:

1) provide additional details on the current price review process followed by the Board in order to make the operation more transparent;
2) assist interested parties to better prepare to make specific suggestions for change; and,
3) solicit more feedback from stakeholders on specific ways that this process can be improved.

Most comments received during the recent consultations concerned the review of the introductory prices of new patented medicines. The paper will therefore focus on the PMPRB's review of new drug products. The Board plans to make this paper available to stakeholders in the fall of 1998.

The Board will also establish a working group to review the discussion paper and make recommendations for the Board to consider on changes to the price review process. The composition of the working group, which will include representatives of the Board's various stakeholder groups, will be announced following the November 20, 1998 Stakeholder's Meeting. **It is hoped that the first meeting of this working group can be held early in 1999**. This same working group will also be asked to review the PMPRB's price review methodology for category 3 drugs.

The following is a preliminary list of some of the issues and possible solutions that will be dealt with in the Price Review Process Discussion Paper.

THE ISSUES AND THE POSSIBILITIES

Communication of information concerning the price review to stakeholders:

- The Board will begin publishing a monthly list of new patented medicines this fall.
- Should we publish the New Medicine Review Report of the Human Drug Advisory Panel (HDAP) for all products for which a category 2 submission has been filed and reviewed?
- Should we publish the comparator drugs and comparable dosage regimens used when a Therapeutic Class Comparison (TCC) is conducted?

Broadening the expertise applied in the review process:

- Is there a need to expand or change the composition of the HDAP to improve the review of the scientific evidence?
- Are clearer criteria needed as to when experts will be consulted, how they will be selected and how their opinions will be incorporated in the review? When in the review process is it necessary to consult with other experts? Is it required for all reviews?

Stakeholder participation in the categorization of new medicines and selection of comparable medicines and dosage regimens:

- Should stakeholders, and in particular the provincial/territorial ministers of health, be given a greater opportunity to make submissions on a new medicine review within a limited time period? If so, how should this be done?
- Is the public notice and comment approach used by the Board in the Humalog matter a useful model for future cases?

Access to the Human Drug Advisory Panel (HDAP) by patentees and other stakeholders:

- As the views of the HDAP are recommendations to the Board rather than decisions, and if they are made public, would it be appropriate or necessary to allow patentees and/or other stakeholders, the opportunity to make submissions in person to the HDAP? If so, what mechanisms would be appropriate to ensure that the process is fair but not subject to abuse and inappropriate delay?
- Would an open public forum for HDAP deliberations be more appropriate? If so, how could this be achieved efficiently?

Appeal process if the patentee disagrees with the conclusions of Board staff:

- Are there alternatives to the current process whereby the only appeal of a staff conclusion is through a Board hearing on excessive price?
- Would transparent operating procedures, to be applied to both patentees and Board staff, be adequate to manage the lengthy debates which currently take place in some cases?
- If questions regarding the application of the Guidelines to a particular patented drug are outstanding after a fixed period of time, should they be referred automatically to the Board for a public hearing? Could this approach also be used for pre-sales advisory assistance or applications for an Advanced Ruling Certificate?

Improving the efficiency and timeliness of the review process:

- Should time frames be established for the submission of scientific and other information to discourage the practice of some patentees to submit information in "dribs and drabs"? In turn, should the PMPRB establish service standards for the review times for new patented drugs?
- To facilitate the process, should the Board have access to the same information filed by manufacturers with the Therapeutic Products Programme, Health Canada?
- Is there a need for the PMPRB to review submissions for category 2 classification if the prices of new products are found to be within the Guidelines based on the TCC test?

CONCLUSION

If you have any comments or are interested in participating in the working group, please contact the Secretary of the Board:

Box L40
Standard Life Centre
Suite 1400
333 Laurier Avenue West
Ottawa, Ontario
K1P 1C1

Toll-free number: 1-877-861-2350
Direct line: (613) 954-8299
Fax: (613) 952-7626
E-mail: sdupont@pmprb-cepmb.gc.ca

[Attachment to the *Road Map for the Next Decade*]

INTRODUCTION

During the Patented Medicine Prices Review Board's recent consultations, several stakeholders raised questions regarding the introductory prices of category 3 new drugs. There appears to be a consensus that the criteria used by the Board for reviewing the prices of these drugs require re-examination.

Some said that a review is necessary to ensure that Canadians are receiving good "value"; they argued that too many "me-too" drugs are being introduced into the Canadian health care system at prices which may not reflect their value. On the other hand, industry representatives stated that the guidelines for category 3 drugs are too restrictive.

This paper provides a preliminary outline of the important issues raised by stakeholders during the Board's consultations. The Board is establishing a working group in the fall of 1998 to make recommendations for consideration by the Board on changes to the price review process. This same working group will be asked to address issues concerning the price review methodology for category 3 drugs.

Many stakeholders encouraged the Board to publish more information on the application of its guidelines to new patented drugs. It was suggested that the price review process could be made more transparent for consumers by providing some examples. In response, this paper provides a brief overview of how Therapeutic Class Comparisons (TCC) are conducted and presents the TCC's used to review the price of three category 3 drugs as examples. These case studies are intended to allow readers to better understand the price review process and the issues raised during the consultations.

Summary of Issues Raised

Few stakeholders stated that the current guidelines for category 3 patented medicines are appropriate in all cases.

Many stakeholders (e.g. provincial and territorial governments, consumer groups and patient advocacy groups) were concerned that the price of a new patented drug in category 3 may be as high as the most expensive drug in the therapeutic class. In particular, there were concerns that this standard is inappropriate for drugs that offer no therapeutic improvement over existing drugs. Many people refer to such drugs as "me-toos". There were also concerns that a high-priced drug holding a small share of the market, or a limited place in therapy, may be the most expensive drug in a TCC and therefore set an upper price limit for non-breakthrough medicines that is too high or inappropriate.

The pharmaceutical industry, on the other hand, was concerned that the current guidelines limit the prices for newer medicines to the prices of older, and in some cases, less effective medicines. They argued that the guidelines do not recognize that some new drugs in category 3 may offer incremental improvements over existing ones. It was also argued that there is a need to

develop a system that better recognizes the incremental progression of drug discovery. In addition, some expressed concerns that a more restrictive price review methodology would force manufacturers to delay the introduction of new drugs.

A number of stakeholders suggested the "value" of a new category 3 medicine should be considered in reviewing its introductory price, in other words, that its cost effectiveness be taken into consideration. The possibilities for greater use of pharmacoeconomic analysis for purposes of the guidelines will be the subject of a separate study and will form part of the PMPRB Research Agenda.

Some Specific Suggestions from Stakeholders

Under the Board's existing Guidelines, the introductory price set by the patentee for a category 3 new drug product will be presumed to be excessive if it exceeds the prices of all of the comparable drug products based on a Therapeutic Class Comparison (TCC) test. In their submissions, stakeholders offered a number of possible alternatives. Among other things, they suggested that the Guidelines be amended to limit the price of a new drug in category 3 so it cannot exceed:

- the median price, or as an alternative, the average price, of all the drugs in the TCC;
- the price of the most commonly prescribed drug within the TCC;
- the price of the "gold standard" among the comparator drugs. (A clear definition of the "gold standard" would have to be developed. For example is it the therapy that is recommended by evidence-based treatment guidelines; is it the "usual practice"; or is it the "drug of choice");
- an adjusted price based on the "added value" or potential therapeutic improvement of the new drug;
- an adjusted price based on the number of existing drugs in the therapeutic class and/or the relative use of brand name and generic drugs; or
- the lower of the highest price in the therapeutic class and the median or lowest international price for the same drug.

Some suggestions proposed distinguishing among category 3 drugs according to the degree of therapeutic improvement or the number of existing drugs that treat the same disease. In other words, different standards should be applied to different sub-groups of category 3.

Overview of Current Approach to Review Category 3 Drugs

Under the Guidelines, a new patented medicine may be classified as category 3 if:

- it is a new active substance; a new, non-comparable dosage form of an existing medicine; or a new combination of existing medicines; and,
- no submission has been made by the patentee that the product be classified as a substantial improvement ; or,
- a submission made by the patentee fails to demonstrate that the product meets the criteria to be classified as a substantial improvement.

The Guidelines require that the price set by the manufacturer for a category 3 drug product be reviewed by applying the Therapeutic Class Comparison (TCC) test. The price of the new drug will be presumed to be excessive if the cost of treatment with the new drug is higher than the maximum cost of treatment of existing drugs which are similar and used to treat the same disease. (See the *PMPRB's Compendium of Guidelines, Policies and Procedures* for a more complete description of the guidelines and the policies on therapeutic class comparisons.)

Therapeutic Class Comparisons

The Guidelines describe the TCC test as comparing the prices of drug products that are "clinically equivalent" and are sold in the same markets at prices that the Board considers not to be excessive.

The objective of the criteria applied in the selection of comparable drug products for the TCC is to identify drug products that are most similar to the new patented drug product. Comparators are generally selected from among existing drug products that:

- are used to treat the disease(s) and/or patient group(s) targeted by the approved indication of the new patented product;
- are in the same therapeutic/pharmacological class (under the Guidelines, comparators are generally restricted to drugs found at the same 4th level of the Anatomical Therapeutic Classification (ATC) system); and
- are of the same or comparable dosage forms of the drug product under review.

The patent status of comparator drugs, or the length of time they have been on the market, are not considerations in the selection process. In other words, the TCC will include brand name and generic products that meet the selection criteria; "old drugs" that are still being used are not excluded because of their age.

The objective of the TCC is to produce an "apples to apples" comparison between the drug product under review and the selected comparable drug products. The Guidelines call for consideration of the dosage regimen, and other clinically relevant variables required to produce a "clinically equivalent effect". The dosage regimens identified "for comparison purposes will not normally be higher than the maximum of the usual recommended dosage". For a complete description of the selection of comparators and comparable dosage regimens for the TCC, see the *Compendium*, Scientific Review Procedures.

The Board contracts drug information centres to assist in this work. Advice is sought from the Board's Human Drug Advisory Panel (HDAP) in more difficult cases or when the recommended TCC is contested by the patentee.

For purposes of the introductory price review, the Board uses the price information provided by the patentee pursuant to the *Patented Medicines Regulations* showing the average transaction price of the new medicine, net of discounts and rebates. Prices of the comparator products are also obtained from the information filed by patentees in the case of a patented drug, and from publicly available sources of price information for non-patented drugs. Under the Guidelines, the Board ordinarily uses the Ontario Drug Benefit Formulary because previous experience has shown that its prices most closely approximate the average transaction prices for patented drugs.

Most often, particularly for drugs that are used for chronic therapy, a cost per day will be calculated. Differences in the course of treatment among comparators will be considered if clinically relevant, e.g., in acute situations.

Examples of Therapeutic Class Comparisons

Recently, the Federal/Provincial/Territorial Task Force on Pharmaceutical Prices asked the Board to report specifically on how its guidelines had been applied in the review of the prices of three new drugs introduced between 1995-97: Cozaar, Fosamax, and Lipitor.

The TCC's conducted for these drugs are included here for information purposes to illustrate the application of the guidelines to category 3 drugs. In all three cases, the introductory prices set by the patentee were found to be within the Guidelines; the cost of therapy with the new product was lower than the cost of therapy of the existing drugs included in the TCC.

The comparators and the pricing information used in the TCC examples presented reflect the situation at the time the drug product was first introduced in Canada.

Cozaar (losartan)

Cozaar (losartan) is sold by Merck Frosst Canada. It was introduced in Canada in September 1995. The introductory prices set by the patentee for each strength were reviewed by the Board and found to be within the Guidelines; the cost per day of Cozaar was found to be lower than the cost per day of treatment of available ACE-inhibitor drugs.

Losartan was the first drug of a new therapeutic class, known as "angiotensin II receptor antagonists". It is indicated for the treatment of high blood pressure. It was introduced in 25 mg and 50 mg tablets; recently, a 100 mg strength was introduced. The example provided looks at the comparators used in the price review of Cozaar 50 mg.

The following information was taken into consideration in setting out the TCC:

- In accordance with the Guidelines, it was necessary to look at other ATC classes for relevant comparators since losartan was the first entry in a new 4th level ATC class. Other drugs used to treat high blood pressure include ACE-inhibitors; beta-blockers; calcium channel blockers and diuretics.

- The Guidelines state that the selection criteria will include indication and therapeutic use and may include other factors such as mode of action, spectrum of activity or chemical family. The TCC for losartan was restricted to a comparison with the ACE-inhibitor drugs. The information reviewed suggested that they were the most relevant comparators; both the ACE-inhibitors and angiotensin II receptor antagonists act on the renin-angiotensin system to lower blood pressure (same 3rd level ATC) and there are clinical trials comparing drugs from the two classes.

- All comparators are solid oral dosage forms.

Cozaar: Comparison to other drugs used in the treatment of high blood pressure

Drug (*Brand name*)	Dosage regimen	Cost per day[1]
Losartan (*Cozaar*)	50 mg daily	$1.10
Benazapril (*Lotensin*)	20 mg twice daily	$1.56
Captopril *(various brands)*[2]	75 mg, 3 times a day	$2.70 - 4.90
Cilazapril (*Inhibace*)	2.5 mg twice daily	$1.36
Enalapril (*Vasotec*)	10 mg twice daily	$1.92
Fosinopril *(Monopril)*	20 mg twice daily	$1.90
Lisinopril (*Prinivil, Zestril*)	20 mg twice daily	$1.94
Quinapril (*Accupril*)	20 mg twice daily	$1.64
Ramipril (*Altace*)	5 mg twice daily	$1.50

1 This medication is administered on a chronic basis, therefore the cost per day was used as the basis for cost comparison with the comparators.

2 Including generics.

NB: Drug cost based on publicly available prices in the Ontario and/or Québec formulary.

Fosamax (alendronate)

Fosamax (alendronate) is sold by Merck Frosst Canada and was introduced in Canada in 1996. The introductory prices set by the patentee for each strength were reviewed by the Board and found to be within the Guidelines; the price of Fosamax was found to be within the range of the prices of existing drugs with the same therapeutic use.

Alendronate belongs to a class of drugs known as "the bisphosphonates". When it first came on the Canadian market, it was approved by Health Canada for use in the treatment of osteoporosis and Paget's Disease. Later it was approved for the prevention of osteoporosis. It is available as a 5 mg, 10 mg and 40 mg tablet. The different strengths have different therapeutic uses. For example, the 10 mg strength is used to treat osteoporosis. The example provided looks at the TCC used in the price review of Fosamax 10 mg.

The following information was taken into consideration in setting out the TCC:

- Alendronate was the 4th entry in the "bisphosphonates" therapeutic class. In 1996, the use of bisphosphonates was a relatively new treatment approach for osteoporosis. Only one other bisphosphonate, etidronate, was being used for this indication. Didrocal (combination of etidronate and calcium) was the first oral bisphosphonate to be approved by Health Canada for the treatment of osteoporosis.

- Other drug therapies used for the treatment of osteoporosis include hormone replacement therapy (HRT; oral estrogens and estrogen transdermal patches) and calcitonin (injectable). In practice, HRT is considered therapy of first choice although it has not been approved for that indication by Health Canada[1]; calcitonin and the bisphosphonates are second line therapies.

- The only published comparative clinical trial available for alendronate at the time of the review was against calcitonin; this trial suggested that alendronate is an improvement over calcitonin.

- The Guidelines provide that comparable medicines used for purposes of a TCC "are clinically equivalent in addressing the approved indication that is anticipated to be the primary use of the new drug product under review". The Guidelines state that while the comparators will normally be selected from the same 4th level ATC class, the selection criteria will include indication and therapeutic use and may include other factors such as mode of action, spectrum of activity or chemical family.

---

[1] We are unaware that any manufacturer of hormone replacement therapies has submitted the available scientific evidence to Health Canada to seek approval for treatment of osteoporosis.

- In view of the foregoing, the HDAP recommended that the TCC for Fosamax be expanded beyond the 4th level ATC class (i.e. the bisphosphonates) to include HRT and calcitonin.

- Under the Guidelines, comparators will normally be of the same or comparable dosage form as the drug product under review. Estrogens are available in oral forms and transdermal patches. Both the oral and transdermal forms are clinically equivalent. As the transdermal patch is widely used by patients on hormone replacement therapy, it is difficult to argue that transdermal patches should be excluded from the TCC.

- Calcitonin is considerably more expensive than the other drugs and is only available in an injectable form. Medical references consulted show that it is still used in the treatment of osteoporosis, albeit less commonly. Given that the only comparative clinical trial for alendronate compared it to calcitonin and that the most commonly prescribed therapy (i.e. HRT) is not approved by Health Canada for this indication, it was difficult to argue that calcitonin should be excluded from the TCC.

- It is recognized that, with all of the drugs in the therapeutic class comparison, oral supplementation of calcium and Vitamin D is recommended in clinical practice. Since this is common to all therapies, the costs were not factored into the TCC.

Fosamax: Comparison to other drugs for treatment of osteoporosis

Drug (*Brand name*)	Dosage regimen[1]	Cost of 90-day treatment[2]
Alendronate (*Fosamax*)	10 mg daily	$157.95
Calcitonin (*Calcimar, Caltine*)	100 IU injection daily	$735.25 - 969.03
Conjugated estrogens (*CES, Congest, Premarin*)	0.625 mg daily	$ 38.22 - 42.39
Estradiol (*Estrace*)	2 mg daily	$ 62.91
Estradiol patch (*Estraderm*)	100 mcg patch-2 per week	$ 97.94
Etidronate/calcium (*Didrocal kit*)	400 mg/day for 14 days + 1250 mg for 76 days	$ 57.67

1 The various dosage regimens as described in the approved product monographs were taken into account in determining comparable dosage regimens.

2 As one of the comparators is available as a 90-day kit (Didrocal), a 90-day course of treatment was used as the basis for the cost calculation.

NB: Drug cost based on publicly available prices in the Ontario and/or Québec formulary.

Lipitor (atorvastatin)

Lipitor (atorvastatin) is sold by Warner-Lambert Canada. It was introduced in Canada in March 1997. The introductory prices set by the patentee for each strength were reviewed by the Board and found to be within the Guidelines; the price of Lipitor was within the range of the prices of the other "statins" already on the market.

Atorvastatin is the 5th entry in the therapeutic class referred to as the "HMG CoA reductase inhibitors" (also known as "the statins"). It is used to reduce cholesterol and triglyceride levels in the blood, a condition referred to as hyperlipidemia. It is supplied in tablets of 10 mg, 20 mg and 40 mg. The example provided looks at the comparators used in the price review of Lipitor 10 mg.

The following information was taken into consideration in setting out the TCC:

- The types of drugs that are used for this indication include the statins, fibrates, bile acid sequestrants and nicotinic acid;

- In accordance with the Board's Guidelines, the TCC for Lipitor was limited to the other drugs in the same 4th level ATC class i.e. the other statins; all comparators are solid oral dosage forms;

- The introductory prices of the other "statins" were reviewed previously by the Board and found to be within the Guidelines. Mevacor (lovastatin) was the first statin to be reviewed by the Board. It was classified in 1988 as a category 2 drug product. The prices of other drugs used to reduce cholesterol and triglycerides were taken into consideration when the first statins were reviewed.

- Lipitor (atorvastatin) may have a greater effect on triglyceride levels than the other statins. Nevertheless, all statins are considered to be clinically comparable for purposes of the TCC.

Lipitor: Comparison to other drugs used in the treatment of hyperlipidemia

Drug (*Brand name*)	Dosage regimen	Cost per day[1]
Atorvastatin (*Lipitor*)	10 mg daily	$1.60
Fluvastatin (*Lescol*)	20 mg daily	$0.75
Lovastatin (*Mevacor*)	20 mg daily	$1.73
Pravastatin (*Pravachol*)	10 mg daily	$1.51
Simvastatin (*Zocor*)	10 mg daily	$1.80

[1] This medication is administered on a chronic basis, therefore the cost per day was used as the basis for cost comparison with the comparators.

NB: Drug cost based on publicly available prices in the Ontario and/or Québec formulary.

[Attachment to the *Road Map for the Next Decade*]

PURPOSE

To consult with stakeholders on the Board's proposal to introduce a complaints-driven process for the price regulation of patented veterinary drug products.

BACKGROUND

As a result of a series of federal government initiatives such as Program Review I, Program Review II and Getting Government Right, the PMPRB began to review and re-evaluate its activities in order to identify areas where it could streamline its processes in order to become more efficient in the manner it fulfills its legislated mandate.

To conduct this exercise, federal departments and agencies were given six criteria against which they were to perform their evaluation. These criteria were:

- **Public Interest**: to determine whether the activity continued to serve a public interest.
- **Role of Government**: whether there is a continued legitimate and necessary role for the federal government in the particular area of the activity.
- **Federalism**: whether the federal government's role in the area is appropriate or should the responsibility be transferred to the provinces.
- **Partnership**: whether the activity or components of it could be provided by the private sector.
- **Efficiency**: how could the efficiency of the program or activity be improved.
- **Affordability**: whether it is financially feasible to continue the activity and if not which one should be abandoned.

Following this review, an alternative approach to regulating the prices of patented veterinary medicines was one of the activities identified by the PMPRB as being a possible area for increasing efficiency.

In the spring of 1994, the PMPRB began discussions on alternative approaches to regulating prices of patented veterinary medicines. In July 1994, the Canadian Animal Health Institute (CAHI) submitted to the PMPRB a discussion paper intended to provide an overview of the inherent differences between the practices of veterinary and human use medicine.

In 1995, the PMPRB retained the George Morris Centre to review the veterinary industry as a whole in order to obtain a better understanding of the veterinary medicines market. In the spring of 1997, the PMPRB undertook informal consultations on the report which the George Morris Centre submitted in late 1996. The report concluded that the dynamics of the veterinary medicines industry would act in concert to control drug prices even with a less active involvement on the part of the PMPRB.

On April 8, 1997 CAHI filed another submission providing suggestions for an alternative approach in regulating prices of patented veterinary medicines and they reiterated that submission during the Board's recent consultations, including the Policy Hearing on April 30, 1998.

The PMPRB's review and consultations on these reports have confirmed that there are inherent differences in the manner that veterinary drug products prices are influenced as compared to drugs for human use. The dynamics of the veterinary industry are such that even if the PMPRB were to take a less active role in the price regulation of patented veterinary medicines, these would act in concert to control their prices.

In addition to these considerations, it is interesting to note that the parliamentary debates leading to the changes to the *Patent Act* and the creation of the PMPRB show that people were concerned with drugs for human use and there was little, if any, discussion about drugs for veterinary use. The PMPRB's policies and Guidelines have been developed from the perspective of drugs for human use and that is the focus of its major stakeholders. Drugs for veterinary use represent a small part of the drugs under the PMPRB's jurisdiction. Of the 99 new patented medicines introduced in 1997, only five were patented veterinary products. Similarly, with respect to manufacturers' revenues in 1997, revenues for new and existing patented medicines for human use were approximately $3.6 billion or 97.2% of the total, as compared to $0.1 billion or 2.8% for new and existing patented veterinary products.

The PMPRB is of the view that these considerations warrant adopting a process which will allow the PMPRB to focus its resources on patented medicines for human use. Accordingly, the PMPRB believes that adopting a complaints-driven process for the price regulation of patented veterinary medicines will achieve this by allowing for more efficient use of the PMPRB's constrained resources.

COMPLAINTS-DRIVEN PROCESS

The elements of the proposal include:

1. Lessening of the Regulatory Burden

The process is geared towards alleviating the regulatory burden upon veterinary patentees by modifying the filing requirements and their frequency. Veterinary patentees would be required to continue to fulfill the filing requirements as to the identification of new patented products (Form 1), the provision of research and development expenditures information (Form 3) and pre-sale notifications as per section 82 of the *Patent Act* (Act). However, as it relates to the filing frequency of price and sales information (Form 2) for existing medicines (which veterinary patentees are currently providing every 6 months) this would be modified by requiring their submission on an "as requested" basis only.

2. Triggering of Price and Sales Information (Form 2) Filing Requirements

Under this proposal, the PMPRB will not actively monitor and review prices of patented veterinary drug products currently on the market. However, upon receiving a substantiated complaint, the veterinary patentee will be requested to file, within a stipulated time frame, price and sales information (Form 2). These data will enable staff to investigate and make appropriate recommendations to the Chairperson in accordance with the PMPRB's Compliance and Enforcement Policy.

3. Price Reviews for New Patented Veterinary Medicines

a) The PMPRB will review the prices of new patented veterinary medicines only. Existing patented veterinary medicines will only become an issue where a substantiated complaint is received (as described in 2 above).

   In the price review of a new patented veterinary medicine, veterinary patentees will continue to file Form 1 and will also report the proposed introductory price of the product.

b) For purposes of added flexibility, PMPRB staff in the conduct of price reviews of patented veterinary medicines, will not be confined to a strict application of the Excessive Price Guidelines. Rather, PMPRB staff will be guided by the price determination factors in section 85 of the Act. The PMPRB's experience in applying the Excessive Price Guidelines to patented veterinary medicines has revealed that the Guidelines often lack the flexibility required to properly review prices of patented veterinary medicines given the various peculiarities of the veterinary drug market.

c) In order to ensure the transparency of this new way of performing an introductory price review for new patented veterinary products, the results of the PMPRB staff's findings and conclusions will be published. This way, if stakeholders have any issue or concern with the conclusions, these can be raised with the PMPRB.

d) If, after reviewing an introductory price, the Board receives a complaint disclosing important new information, staff will commence an investigation. If, based on the new information, the introductory price is considered to be excessive, the matter will be referred to the Chairperson for appropriate measures in accordance with the Compliance and Enforcement Policy.

e) If subsequent to the review of the introductory price of a new patented veterinary drug, the PMPRB receives evidence showing the patentee is actually selling at a price which exceeds the price reviewed, staff will begin an investigation. Following an investigation staff will prepare a report and submit it to the Chairperson with recommendations for appropriate remedial measure under the Act. Where a hearing is initiated, such evidence may be considered as demonstrating a policy of selling at an excessive price.

f) Where the price is not found to be excessive following an investigation, a report to the Chairperson will be prepared for closure. The resolution of all investigations will be published by the Board with reasons provided.

4. Written Undertaking

During the transitional period, veterinary patentees will be required to provide the PMPRB with a written undertaking. Given that Form 2 price and sales information/data would be filed only upon a request from the PMPRB, patentees will be asked to undertake to continue to maintain price and sales information in the manner required by the *Patented Medicines Regulations* - in the event the PMPRB were to request it, and to diligently file the information within the time stipulated in a request. As well, patentees will undertake, in accordance with section 82 of the Act to pre-notify the PMPRB of their intent to offer for sale a product not previously offered for sale in Canada and its proposed price. The patentee will thereby agree to allow the Board to publish the proposed introductory price for new patented veterinary products.

The waiving of the usual regulatory filing requirements as described above is contingent upon the veterinary patentee providing a written undertaking to the PMPRB.

5. Transitional Period

The complaints-driven process will have a transitional period of three years. This period of time will permit the PMPRB to evaluate the effectiveness of the system and determine whether it should be continued, whether the PMPRB should recommend complete deregulation of veterinary drug product pricing, or whether the PMPRB should revert back to the current manner of regulating prices of patented veterinary medicines.

OTHER CONSIDERATIONS

Substantiated Complaints

It is to be noted that the PMPRB does not regulate prices of patented veterinary products at the retail level but rather the ex-factory gate prices at which manufacturers sell the products. Under the proposed complaints-driven process, the PMPRB staff would begin an investigation on the pricing at which a manufacturer is selling a patented veterinary medicine only upon a substantiated complaint being received. A substantiated complaint will be accompanied by evidence, oral or written, which raises the potential for an excessive pricing issue relating to the prices at which a manufacturer is selling a patented veterinary product and which, therefore, triggers the need for the PMPRB staff to open an investigation.

Public Interest / Efficiency

In light of the differences between the veterinary drug and human use drug markets, the PMPRB's constrained resources and increasing demands on the PMPRB staff to focus on drugs for human use, it is believed that the public interest would be better served by adopting a complaints-driven process for patented veterinary medicines.

Indeed, this will permit the PMPRB to focus on human use drugs in light of stakeholders' concerns with the rising costs of drug products for human use. Regulating prices of patented veterinary drug products in the same way as human drugs diverts from the attention which could otherwise be dedicated to the latter. Furthermore, since the inception of the PMPRB, the Board has not received any complaints in relation to the prices of patented veterinary drug products.

Effective Date of Proposal

If, after completing its consultations and having had an opportunity to consider stakeholders' comments, the Board is satisfied that it should proceed with the complaints-driven process on prices of patented veterinary medicines, this process would become effective January 1, 1999 for new drugs and sales after that date.

Thus, effective January 1999, veterinary patentees would continue to file only Form 1 and the proposed price for a new drug but would not be required to file price and sales information (Form 2) for data year 1999. However, veterinary patentees will need to file, by January 30, 1999, price and sales information for pricing periods up to December 31, 1998.

It should be noted that veterinary patentees will continue to file with the PMPRB identification of new patented products sheet (Form 1), research and development expenditures information (Form 3) and pre-sales notifications in accordance with section 82 of the *Patent Act*.

COMMENTS

The PMPRB is initiating formal consultations on this proposal with the release of this paper and the *Road Map for the Next Decade*. Your comments on this proposal should be provided to the PMPRB by November 20, 1998.

Your comments should be addressed to Secretary of the Board:

Standard Life Centre
Box L40
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Toll-free number: 1-877-861-2350
Direct line: (613) 954-8299
Fax: (613) 952-7626
E-mail: sdupont@pmprb-cepmb.gc.ca

0 78787 67538 4

Oxford
ESSELTE
10%